



The Pandemic Influenza Preparedness Framework as a ‘specialized international access and benefit-sharing instrument’ under the Nagoya Protocol

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ABSTRACT

The World Health Organization (WHO) is starting to come to terms with the public health implications of the United Nations Convention on Biological Diversity (CBD) and its supplementary Nagoya Protocol about genetic resource access and benefit-sharing (ABS). Since 2017 there have been calls to recognise the WHO’s Pandemic Influenza Preparedness (PIP) Framework as a specialized international ABS instrument under the Nagoya Protocol. This article will examine whether the PIP Framework meets the criteria of a specialized international ABS instrument as laid out in a 2018 study commissioned by the Subsidiary Body on Implementation to the CBD. Our analysis concludes that, while the PIP Framework meets the specialization criteria, it fails to meet the supportiveness criteria and does not provide legal certainty for pandemic influenza virus ABS, and therefore cannot constitute a specialized instrument under the CBD. Furthermore, we demonstrate that recognition of the PIP Framework as a specialized instrument would not mean that the CBD and Nagoya Protocol no longer apply to influenza viruses with human pandemic potential as has been asserted, rendering the relationship between the three international agreements unclear. As the WHO grapples with how to regulate access to other (non-influenza) human pathogens and the fair and equitable sharing of benefits associated with their use, a full appreciation of what ABS means when applied to pathogens is essential.

Keywords: Nagoya Protocol; PIP Framework; specialized instrument; Convention on Biological Diversity; treaty interaction; international law.

INTRODUCTION

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (Nagoya Protocol) is a binding international agreement that aims to ensure that the benefits arising from the utilisation of genetic resources are shared in a fair and equitable way, by governing access to those genetic resources, and by ensuring that justice, environmental concerns and sustainable development are incorporated into the transfer of those genetic resources from host countries to resource users. Article 4 of the Nagoya Protocol seeks to clarify its relationship with existing and future international agreements, recognising that parties may want to adopt certain access and benefit-sharing (ABS) measures that are specific to specialized subsets of genetic resources.¹ Articles 4(2) and 4(4) of the Nagoya Protocol thus create a designation of 'specialized international access and benefit-sharing instrument', or 'specialized instrument'. Unfortunately, there is no further guidance as to the criteria that such an instrument would need to meet in order to be considered a specialized instrument for the purposes of article 4 of the Nagoya Protocol.

There have been calls for the World Health Organization's (WHO) Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits (PIP Framework) to be recognised as a specialized international ABS instrument under article 4 of the Nagoya Protocol,² but it is not yet clear whether the PIP Framework could be considered to be consistent with, and supportive of, the objectives of the United Nations (UN) Convention on Biological Diversity (CBD) and Nagoya Protocol. This article seeks to answer this question. It begins with an explanation of the PIP Framework and how it operates.³ It next examines whether the PIP Framework can be considered a specialized international ABS instrument under article 4 of the Nagoya Protocol in accordance with the criteria outlined in the 2018 'Study into Criteria to Identify a Specialized International Access and Benefit-Sharing Instrument, and

1 Articles 4(2) and 4(3), Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity 2010, UNEP/CBD/COP/10/27.

2 WHO, Review of the Pandemic Influenza Preparedness Framework: Report by the Director-General, A70/17, 10 April 2017, 23, Annex, Recommendation 36; WHO, Implementation of the Nagoya Protocol and Pathogen Sharing: Public Health Implications, EB140/15, 8 January 2017, 23.

3 For an analysis on the PIP Framework's SMTAs, see Michelle Rourke, 'Access by design, benefits if convenient: a closer look at the Pandemic Influenza Preparedness Framework's Standard Material Transfer Agreements' (2019) 97(1) *The Milbank Quarterly* 91.

a Possible Process for its Recognition' commissioned by the CBD's Subsidiary Body on Implementation⁴ – the closest the international community has to a set of rules for specialized instrument recognition.

In doing so, we argue that the PIP Framework fails to meet the criteria to be recognised as a specialized instrument under article 4 of the Nagoya Protocol, as it does not adequately support the objectives of the CBD. We conclude that recognition of the PIP Framework as a specialized instrument would not mean that the CBD and Nagoya Protocol no longer apply to all influenza viruses with human pandemic potential, rendering the relationship between the three international agreements unclear. Furthermore, as the WHO decides how to regulate access to other (non-influenza) human pathogens and the fair and equitable sharing of benefits associated with their use, notably through a possible Pandemic Treaty, we intend for this article to contribute to a fuller understanding of the PIP Framework's ABS elements and the lessons that can be drawn about the use of the ABS mechanism in public health more generally.

SPECIALIZED INTERNATIONAL ABS INSTRUMENTS AND THE NAGOYA PROTOCOL

The Nagoya Protocol is a supplementary agreement under the UN CBD,⁵ building on article 15 of the CBD that affirmed that countries have sovereignty over their genetic resources and have the authority to implement national legislation regulating their access and

4 CBD, Study into Criteria to Identify a Specialized International Access and Benefit-Sharing Instrument, and a Possible Process for its Recognition: Note By The Executive Secretary, CBD/SBI/2/INF/17, 29 May 2018; note that in 2013 Marie Wilke published two chapters that posed similar questions – whether the PIP Framework could be considered a specialized instrument under the Nagoya Protocol and whether it met the criteria of effectiveness and fairness. Her analyses will be referred to throughout. See Marie Wilke, 'A healthy look at the Nagoya Protocol – implications for global health governance' in Elisa Morgera, Matthias Buck and Elsa Tsioumani (eds), *The 2010 Nagoya Protocol on Access and Benefit-sharing in Perspective* (Martinus Nijhoff 2013); Marie Wilke, 'The World Health Organization's Pandemic Preparedness Framework as a public health resources pool' in Evanson Chege Kamau and Gert Winter (eds), *Common Pools of Genetic Resources – Equity and Innovation in International Biodiversity Law* (Routledge 2013). Since 2013 the discussions about what constitutes a specialized instrument have progressed within the CBD forum and the most recent study commissioned by the CBD starts to put a comprehensive structure around what does and does not constitute a specialized instrument. This analysis extends and updates Wilke's by using the newly stated criteria.

5 The CBD was opened for signature on 5 June 1992 and entered into force on 29 December 1993. The Nagoya Protocol to the CBD was adopted on 29 October 2010 and entered into force on 12 October 2014.

use.⁶ The effect of the Nagoya Protocol was to elaborate on some of the uncertain definitions (such as 'derivatives' and 'utilisation'), develop some of the concepts (such as traditional knowledge associated with genetic resources) and introduce some of the machinery provisions for implementing the CBD (such as checkpoints, certificates of origin and so on). There are currently 193 contracting parties to the CBD and 123 parties to both the CBD and Nagoya Protocol,⁷ essentially establishing three schemes: the CBD alone (73 Contracting Parties); the CBD plus Nagoya Protocol (123 Parties); and neither the CBD nor the Nagoya Protocol (United States and Holy See). As a minimum under the CBD and Nagoya Protocol, obligations include obtaining prior informed consent⁸ and coming to mutually agreed terms about the use of genetic resources,⁹ which can include the sharing of monetary or non-monetary benefits such as technology transfer, training and intellectual property.¹⁰ This exchange of access to sovereign genetic resources in return for benefits associated with their use is known as access and benefit-sharing (ABS). While the Nagoya Protocol recognises that ABS can be achieved through multilateral mechanisms,¹¹ both the CBD and Nagoya Protocol envisage a bilateral contractual agreement between providers and users of genetic resources as the default ABS mechanism.

Article 4(2) provides:

Nothing in this Protocol shall prevent the Parties from developing and implementing other relevant international agreements, including other specialized access and benefit-sharing agreements, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.¹²

Article 4(4) of the Nagoya Protocol continues:

Where a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the Convention and this Protocol, this Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument.¹³

Inherent within article 4 is the acknowledgment that designation as

6 Art 15(1), Convention on Biological Diversity (Rio de Janeiro, 5 June 1992) 1760 UNTS 79, *entered into force* 29 December 1993.

7 As at 13 April 2020. See [List of Parties](#).

8 Art 15(5).

9 Art 15(4).

10 Art 15(7).

11 Art 10.

12 Art 4(2).

13 Art 4(4).

a specialized instrument is a limited category. The Nagoya Protocol applies as the default ABS mechanism, and a specialized instrument can only deviate from the CBD/Nagoya Protocol ABS regime providing the instrument is 'supportive of and do[es] not run counter to the objectives of the Convention and this Protocol'.¹⁴ Recognition that an agreement is a specialized international ABS instrument is significant in international law, not only because of the vague and undefined processes by which this is to occur, but because such recognition significantly alters the scope and operation of an already in-force treaty. If an agreement is classed as a specialized instrument under article 4 of the Nagoya Protocol, then the Nagoya Protocol no longer applies to the genetic resources included under that instrument to the extent that specialized instrument is consistent with the Nagoya Protocol.

There are currently two international instruments that might be considered specialized international ABS instruments under article 4 of the Nagoya Protocol.¹⁵ The first is the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA or Plant Treaty) adopted by the UN's Food and Agriculture Organization (FAO) in 2001. The Plant Treaty was specifically developed 'in harmony' with the CBD¹⁶ and governs ABS for a specific subset of agriculturally important plants.¹⁷ The second is the WHO's PIP Framework. The PIP Framework was adopted as a World Health Assembly (WHA) Resolution in May 2011,¹⁸ and outlines ABS arrangements for the subset of influenza viruses that have human pandemic potential,¹⁹ but not for seasonal influenza viruses.²⁰ In this sense, the PIP Framework certainly appears to be a (highly) specialized ABS instrument. However,

14 Art 4(2).

15 Note also that negotiations for an international legally binding instrument (ILBI) under the UN's Convention on the Law of the Sea (UNCLOS) are ongoing and have included ABS measures for the marine genetic resources on the high seas, which may mean that the ILBI could become a specialized ABS instrument of sorts. However, it should be noted that genetic resources found on the high seas are outside the scope of the CBD and Nagoya Protocol, and therefore the ILBI would not require (nor presumably qualify for) recognition as a specialized instrument because the Nagoya Protocol only applies to sovereign genetic resources.

16 Art 1(1), International Treaty on Plant Genetic Resources for Food and Agriculture 2001, 2400 UNTS 303

17 Annex 1, and any other materials included within the Multilateral System (arts 11(1) 11(5) and 15(1)). Some parties to the CBD have already recognised the Plant Treaty as a specialized instrument in their domestic legislation. See WHO EB140/15 (n 2 above) 24.

18 WHO, Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits (PIP Framework) UN Doc A64/VR/10, 24 May 2011.

19 Art 3(1).

20 Art 3(2).

unlike the Plant Treaty, the PIP Framework was not developed to be in harmony with the CBD.²¹ In fact, the PIP Framework does not mention the CBD within its text, despite article 15 of the CBD providing the legal foundation for parts of the PIP Framework.²² Therefore the PIP Framework's potential recognition as a specialized instrument under article 4 of the Nagoya Protocol is all the more complex and significant, given that the PIP Framework could cast the Nagoya Protocol into abeyance in the field of pandemic influenza viruses.

THE GLOBAL SHARING OF INFLUENZA VIRUS SAMPLES

Informal influenza virus sample sharing

Influenza poses a significant risk to the human population. Effectively combating pandemic influenza requires an internationally coordinated response which includes testing, surveillance, the development of antiviral medication and strain-specific vaccines. This is an ongoing process for influenza, as seasonal strains change year to year (genetic drift) and can recombine to produce potentially pandemic strains (pandemic shift) where new influenza subtypes emerge.²³ As a result, the international scientific community has been sharing influenza viruses informally for decades, monitoring the changing genetic sequence of seasonal strains and hoping to detect a pandemic strain before it starts to take hold in the human population. The WHO coordinates the sharing of virus samples between this network of laboratories that has existed in some form since the 1950s.²⁴ The sharing of seasonal and potentially pandemic influenza virus samples between the laboratories of the Global Influenza Surveillance Network (GISN)²⁵ occurred on an informal basis until 2006 when attitudes to informal virus sharing started to shift.

21 The PIP Framework and the Nagoya Protocol negotiations overlapped, with the two processes influencing each other. For a detailed explanation of how these negotiation processes interacted, see Wilke, 'A healthy look at the Nagoya Protocol' (n 4 above).

22 See the section on 'The development of the PIP Framework', page 417 below.

23 Antole Krattiger et al, 'Intellectual property management strategies to accelerate the development and access of vaccines and diagnostics: case studies of pandemic influenza, malaria, and SARS' (2006) 2(2) *Innovation Strategy Today* 67.

24 WHO (n 18 above); as Influenza A viruses infect multiple animal hosts, there is a similar network of laboratories that share animal influenza viruses coordinated by the FAO.

25 Renamed the Global Influenza Surveillance and Response System in 2011.

The development of the PIP Framework

In 2006, in response to the threat posed by H5N1 avian influenza virus, the WHO passed resolution 59.2, which called upon WHO member states to '[d]isseminate to the WHO collaborating centres information and relevant biological materials related to highly pathogenic avian influenza and other novel influenza strains in a timely and consistent manner'.²⁶ At the time, Indonesia had the highest number of infections and deaths from H5N1.²⁷ Despite this, and the established norm of free virus sharing between laboratories of the GISN, Indonesia's sharing of virus samples with GISN fluctuated between openly sharing samples and refusing to share, claiming that Indonesia had sovereign authority over the samples isolated within its territories, and that it was therefore under no obligation to share them with the wider international community.²⁸ In claiming that the virus samples were its sovereign resources, Indonesia invoked the CBD, which states that 'access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources',²⁹ and any access granted 'shall be on mutually agreed terms'.³⁰

This framing helped Indonesia highlight the inequity of being expected to share virus samples with GISN but not being afforded fair access to the vaccines and antivirals developed using those samples,³¹ challenging the notion that the existing system of pandemic influenza preparedness was a global public good.³² Indonesia's then Health Minister Siti Fadilah Supari claimed that the WHO transferred the samples Indonesia provided on to pharmaceutical companies to develop pandemic influenza vaccines, who then patented the vaccine and its components which developing countries could not afford.³³ The basis of this claim was subsequently shown to be correct when it

26 WHO, Application of the International Health Regulations (2005) WHA59.2, 26 May 2006.

27 WHO, Table A 2003–2009, Cumulative number of confirmed human cases for avian influenza A(H5N1) reported to WHO, 2003–2015 (2015).

28 Peter Gelling, 'Indonesia defiant on refusal to share bird flu samples' *New York Times* (New York, 26 March 2015) 12; Endang R Sedyaningsih et al, 'Towards mutual trust, transparency and equity in virus sharing mechanism: the avian influenza case of Indonesia' (2008) 37(6) *Annals of the Academy of Medicine, Singapore* 482.

29 Art 15(5).

30 Art 15(4).

31 Rachel Irwin, 'Indonesia, H5N1, and global health diplomacy' (2010) 3 *Global Health Governance*.

32 Jeremy Youde, *Globalisation and Health* (Rowman & Littlefield 2019) 115.

33 Declan Butler, 'Q&A: Siti Fadilah Supari' (2007) 450(7173) *Nature* 1137; Sedyaningsih et al (n 28 above).

was discovered that virus samples were being transferred from GISN laboratories to pharmaceutical manufacturers without consultation with, or the permission of, the originating country.³⁴ This controversial action forced the WHO to put formal terms around the GISN's virus-sharing practices in what was to become known as the PIP Framework.³⁵ During the negotiations, Indonesia submitted:

[A] framework of benefit sharing is to be developed through agreed terms and conditions to ensure a global stockpile of pre-pandemic and pandemic vaccines, accessibility of vaccine at an affordable price, access to and transfer of technology and know-how for production of vaccines and empowerment and capacity building of vaccine manufacturing in developing countries.³⁶

After four years of negotiations, the PIP Framework was adopted in May 2011.³⁷ It provides for recommendations in two areas: the timely sharing of influenza samples with human pandemic potential between member states and the WHO via the newly renamed Global Influenza Surveillance and Response System (GISRS);³⁸ and the sharing of virus samples with third-party entities that operate outside of the GISRS, such as pharmaceutical and vaccine manufacturers, in return for these external entities sharing benefits with the WHO for distribution to member states in the event of an influenza pandemic.³⁹ Thus, the PIP Framework is ostensibly an ABS framework governing access to viral genetic resources in exchange for the benefits arising from their use.

The Nagoya Protocol to the Convention on Biological Diversity

The CBD was adopted in 1992 and used by Indonesia in 2006 and 2007 as the legal basis for claiming sovereignty over influenza virus samples. Article 15.1 of the CBD 'recogniz[es] the sovereign rights of States over

34 Colin McInnes and Kelly Lee, *Global Health and International Relations* (Polity Press 2012) 193.

35 Jeanette Lange, 'Negotiating issues related to pandemic influenza preparedness: the sharing of influenza viruses and access to vaccines and other benefits' in Ellen Rosskam and Ilinoa Kickbusch (eds), *Negotiating and Navigating Global Health: Case Studies in Global Health Diplomacy* (World Scientific 2012).

36 WHO, Submission of the Government of Indonesia, 'Fundamental Principles and Elements for the Development of a New System for Virus Access and Fair and Equitable Benefit Sharing Arising from the Use of the Virus for the Pandemic Influenza Preparedness' at Interdisciplinary Working Group, 'Sharing of Influenza' A/PIP/IGM/WG/4, 3 April 2008.

37 64th World Health Assembly, Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits (PIP Framework), Geneva, Switzerland: WHO (2011: WHA64.5).

38 Art 5(1).

39 Art 6(11).

their natural resources' and affirms that national governments have 'the authority to determine access to genetic resources'.⁴⁰ The CBD has three objectives:

[1] the conservation of biological diversity, [2] the sustainable use of its components and [3] the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.⁴¹

Indonesia argued that this third objective about accessing genetic resources and sharing the benefits associated with their use (abbreviated as 'access and benefit-sharing', or ABS), applied to viruses that were isolated from within their territorial borders.⁴² Developed countries held that viruses were a threat to biodiversity and not the sort of genetic resource that ought to be regulated by an environmental conservation treaty.⁴³ By adopting the PIP Framework, which 'recognize[d] the sovereign right of States over their biological resources'⁴⁴ the WHO had implicitly accepted the premise of Indonesia's argument:⁴⁵ viruses are the sovereign genetic resources of nation states and are therefore subject to benefit-sharing obligations under the CBD.⁴⁶ The CBD clarifies that this means nation states have the authority to implement domestic measures regulating their genetic resources. Article 3 provides, in part: 'States have, in accordance with the Charter of the UN and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies.'⁴⁷

The negotiations for the PIP Framework at the WHO coincided with negotiations of the Nagoya Protocol at the CBD, however, the text of the PIP Framework remained silent regarding its relationship to both

40 Art 15(1).

41 Art 1.

42 Sedyaningsih et al (n 28 above).

43 See explanations in David Fidler, 'Influenza virus samples, international law, and global health diplomacy' (2008) 14(1) *Emerging Infectious Diseases* 88, 90; Frederick M Abbott, 'An international legal framework for the sharing of pathogens: issues and challenges' (2010) ICTSD Issue Paper No 30, 13–14; Frank L Smith III, 'Insights into surveillance from the influenza virus and benefit sharing controversy' (2012) 24(1) *Global Change, Peace and Security* 79.

44 Art 1(11).

45 Michelle Rourke, 'Restricting access to pathogen samples and epidemiological data: a not-so-brief history of "viral sovereignty" and the mark it left on the world' in Mark Eccleston-Turner and Ian Brassington (eds), *Infectious Diseases in the New Millennium: Legal and Ethical Challenges* (Springer 2020).

46 Michelle Rourke, 'Viruses for sale – all viruses are subject to access and benefit sharing obligations under the Convention on Biological Diversity' (2017) 39(2) *European Intellectual Property Review* 79–89.

47 Art 3.

the CBD and the Nagoya Protocol. This was despite the instruments regulating overlapping subject matter: human pandemic influenza viruses fall under the PIP Framework and are still within the remit of the CBD and Nagoya Protocol. Nevertheless, on the face of it, the PIP Framework does appear to be a specialized ABS instrument because it places rules and obligations around a specific set of genetic resources that also fall within the remit of the CBD and Nagoya Protocol: accessing influenza viruses with pandemic potential and sharing the benefits associated with their use.

The WHO's 2016 internal review of the PIP Framework specifically addressed the interaction of the PIP Framework with the Nagoya Protocol. It stated:

The PIP Framework is a multilateral access and benefit sharing instrument that appears to be consistent with the objectives of the Nagoya Protocol ... the implementation of the Nagoya Protocol may introduce uncertainty in relation to the sharing of influenza viruses, since numerous bilateral transactions could be required to be negotiated, which could delay the access to viruses. As more countries put in place domestic legislation to implement the Nagoya Protocol, the urgency increases to resolve this uncertainty and reduce the risk to global health security.⁴⁸

The concern here is that countries may exercise their sovereignty by choosing to regulate ABS for human pandemic influenza viruses through national measures implementing the binding CBD or CBD/Nagoya Protocol agreements, rather than participating in the WHO's non-binding virus-sharing arrangements under the PIP Framework. In light of this uncertainty, the PIP Review Group recommended that '[t]he PIP Framework should be considered as a specialized international instrument to clarify the implementation of the Nagoya Protocol in relation to pandemic influenza preparedness and response'.⁴⁹ After considering the PIP Review Group's report, the seventieth WHA in 2017 adopted Decision WHA70(10) which 'reaffirme[d] the importance of the PIP Framework' and 'emphasize[d] its critical function as a specialized international instrument' for accessing pandemic influenza viruses and sharing vaccines and other benefits.⁵⁰ That is, it may function as a specialized ABS instrument at times, but it does not have any legal recognition as such.

48 WHO (n 18 above) annex, 22.

49 Ibid 23.

50 Ibid para 2.

THE INTERACTION OF THE PIP FRAMEWORK AND NAGOYA PROTOCOL

The parallel operation of the PIP Framework and Nagoya Protocol does create some confusion. To reiterate, article 3.1 of the PIP Framework states that it 'applies to the sharing of H5N1 and other influenza viruses with human pandemic potential and the sharing of benefits',⁵¹ but functionally, the PIP Framework only applies to those 'H5N1 and other influenza viruses with human pandemic potential' that countries choose to share through the GISRS and thus become 'PIP biological Materials'.⁵² Other samples of H5N1 and other influenza viruses with human pandemic potential exist outside of the GISRS network. They were never part of the network and remain outside of the regulatory reach of the PIP Framework. These virus samples are instead captured under the regulation of 'genetic resources' under article 15 of the CBD and the Nagoya Protocol.⁵³ Because the PIP Framework does not have official recognition as a specialized instrument under article 4(4) of the Nagoya Protocol, the viruses within the scope of the PIP Framework are also covered by the CBD and Nagoya Protocol.⁵⁴ This means that countries that have shared, or would usually share, pandemic influenza viruses through the PIP Framework, might instead choose to enter into bilateral arrangements with a vaccine manufacturer (or other party), removing the WHO as the intermediary, as per their rights under the CBD and Nagoya Protocol. Therefore, the parallel functioning of the PIP Framework and Nagoya Protocol could undermine the whole point of the PIP Framework and the functioning of the GISRS. Official recognition of the PIP Framework as a specialized instrument under article 4(4) of the Nagoya Protocol would theoretically mean that the CBD and Nagoya Protocol no longer apply to those viruses already within the scope of the PIP Framework. Hence the importance of recognition as a specialized instrument and the importance of working out precisely what a specialized instrument should be in order to have it qualify for such recognition.

It certainly appears that the PIP Framework is a specialized international ABS instrument insofar as the international community is using it as such. Between 1 December 2012 and 30 June 2019, 1205 PIP biological materials were recorded in the PIP Framework's

51 Art 3(1).

52 Arts 4(1) and 5(1). Note that not all viruses shared through the GISRS are 'PIP biological materials' as non-pandemic influenza and other viruses are also shared with this network of laboratories.

53 Arts 2 and 15, CBD; Art 3, Nagoya Protocol.

54 Art 4(4).

Influenza Virus Tracing Mechanism (IVTM),⁵⁵ although the number of influenza samples that pass through the GISRS each year far surpasses this number. However, recent problems with accessing influenza viruses through the GISRS indicate that the system is being sidelined in favour of alternative ABS arrangements.⁵⁶ The following analysis of the PIP Framework in light of article 4(4) of the Nagoya Protocol may point to some of the reasons why some users are avoiding it.

CRITERIA FOR SPECIALIZED INTERNATIONAL ABS INSTRUMENTS

In December 2016, the second meeting of the Conference of the Parties to the CBD Serving as the Meeting of the Parties to the Nagoya Protocol (COP-MOP 2) adopted Decision 2/5 on 'Cooperation with other international organizations, conventions and initiatives'.⁵⁷ During the discussions, 'some express[ed] concern over the initiative taken [by the WHO] outside of the [Nagoya] Protocol to clarify its relationship with the PIP Framework'.⁵⁸ Decision 2/5 requested the Executive Secretary of the CBD to 'conduct a study into criteria that could be used to identify what constitutes a specialized international access and benefit-sharing instrument' under article 4(4) of the Nagoya Protocol and investigate 'what could be a possible process for recognizing such an instrument'.⁵⁹ The resulting study⁶⁰ was presented via the Subsidiary

55 WHO, *Pandemic Influenza Preparedness Framework Progress Report 1 January 2018–30 June 2019* (2019) 7.

56 WHO, *Approaches to Seasonal Influenza and Genetic Sequence Data under the PIP Framework*, 14 December 2018, 30; GISAID, *GISAID's Comments on the WHO Report of the Public Health Implications of Implementation of the Nagoya Protocol*, 13 May 2019.

57 CBD, 'Second Meeting of the Conference of the Parties to the Convention on Biological Diversity Serving as the Meeting of the Parties to the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization: Decision 2/5 Adopted by the Parties to the Nagoya Protocol on Access and Benefit-Sharing: Cooperation with other international organization, conventions and initiatives' CBD/NP/MOP/DEC/2/5, 16 December 2016.

58 Stephanie Switzer et al, 'Biodiversity, pathogen sharing and international law' in Stefania Negri (ed), *Environmental Health in International and EU Law: Current Challenges and Legal Responses* (Routledge 2019) 281.

59 CBD (n 57 above) para 3, 2.

60 CBD (n 4 above).

Body on Implementation to the COP-MOP 3 in 2018.⁶¹ The Study into the Criteria to Identify a Specialized International Access and Benefit-Sharing Instrument, and a Possible Process for its Recognition (hereafter 'the Study') outlined nine potential criteria for specialized international ABS instruments under two categories: specialization and supportiveness).⁶² The specialization criteria refer to the extent to which an instrument addresses specific uses of genetic resources which would require a differentiated (from the Nagoya Protocol) and hence specialized approach, whereas supportiveness refers to the extent to which the instrument is consistent with the aims, objectives and approach of the CBD and Nagoya Protocol.

This section addresses the criteria laid out in the 2018 Study with specific reference to the objectives, text and operation of the PIP Framework and its associated Standard Material Transfer Agreements (SMTAs).⁶³ The 2016 Review of the PIP Framework stated that the PIP Framework 'appears to be consistent with the objectives of the Nagoya Protocol'.⁶⁴ This section analyses the extent to which the PIP Framework, as the world's only virus-specific ABS instrument, is actually consistent with the objectives of the Nagoya Protocol by examining each of the Study's criteria in turn, under the Study's categories of specialization and supportiveness. While the Study does not 'necessarily reflect the views of the [CBD] Secretariat'⁶⁵ and the criteria for specialized instruments are still very much under discussion,⁶⁶ it does provide a point of reference for further discussion. A thorough examination of the PIP Framework using these criteria is instructive for those wishing to improve the ABS process for those genetic resources requiring a specialized approach outside of the CBD and Nagoya Protocol's default bilateral contract arrangements.

61 CBD, 'Third Meeting of the Conference of the Parties to the Convention on Biological Diversity Serving as the Meeting of the Parties to the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization: Decision 3/14 Specialized international access and benefit sharing instruments in the context of Article 4, paragraph 4, of the Nagoya Protocol' CBD/NP/MOP/DEC/3/14, 31 January 2019, para 1, 1.

62 CBD (n 4 above) 12–13.

63 Annex 1 (Standard Material Transfer Agreement 1) and annex 2 (Standard Material Transfer Agreement 2), PIP Framework (n 18 above).

64 WHO (n 18 above) annex, 22.

65 CBD (n 4 above) 1.

66 CBD (n 61 above) annex, 2.

Specialization

*An instrument under consideration would be
intergovernmentally agreed upon*

The PIP Framework was adopted as Resolution WHA64.5 by the WHA in May 2011, in accordance with article 23 of the Constitution of the WHO, giving it the status of a 'Resolution of the World Health Assembly'.⁶⁷ Resolutions require a two-thirds majority of the 196 member states before passing. The PIP Framework is certainly intergovernmentally agreed upon 'under the aegis of an international organization created by a treaty'.⁶⁸ But this criterion highlights the perhaps obvious point that the membership of the WHO is not the same membership as that of the Nagoya Protocol, and the Meeting of the Parties to the Nagoya Protocol is likely the only body that could adopt or accept the PIP Framework as a specialized instrument.⁶⁹

An 'instrument' may be either binding or non-binding

The PIP Framework takes the form of a resolution of the WHA, as opposed to a treaty. This is not inherently a limitation to the PIP Framework being recognised as a specialized instrument: the language of article 4(4) is particularly broad in referring to 'instruments' as opposed to 'agreements', implying that the states parties of the Nagoya Protocol anticipated a scenario whereby instruments not grounded in treaty law could constitute a specialized instrument. Thus, the PIP Framework meets the second criterion of the Study.

However, Wilke points out that the PIP Framework's non-binding nature is not irrelevant, as it has implications for the scope of the instrument and the background functioning of the CBD and Nagoya Protocol's ABS regime. Wilke states that the PIP Framework 'only functions as a specialized ABS instrument for influenza viruses where transfers are covered by the Framework's binding contract clauses',⁷⁰ meaning just the ones that countries have chosen to share with the GISRS through the mechanisms created by the PIP Framework. As a result, the CBD and Nagoya Protocol remain the default ABS mechanism regulating the transfer of pandemic influenza viruses that member

67 Constitution of the World Health Organization (New York, 22 July 1946) 14 UNTS 185, *entered into force* 7 April 1948.

68 CBD (n 4) 6.

69 This is the only agreement discussed here with a provision on specialized instruments (the CBD does not have any equivalent provision). Therefore, the acceptances of the PIP Framework as a specialized instrument would likely only impact parties to the Nagoya Protocol.

70 Wilke, 'A healthy look at the Nagoya Protocol' (n 4 above) 126.

states do *not* share with the GISRS through the PIP Framework (as they are free to do).

All this is to say that, if the PIP Framework were binding, it would be likely the default arrangement for the sharing of pandemic influenza viruses; there would be a clear international obligation on member states to share these viruses with the WHO under the PIP Framework. The only point at which parties take on the obligations of the PIP Framework's ABS provisions is when they enter into SMTAs with the WHO, and member states can choose which virus samples to share under the SMTAs.⁷¹ This means that the PIP Framework does not actually create any obligation to share pandemic influenza viruses with the GISRS. Member states can continue to enter into bilateral ABS arrangements under the CBD and Nagoya Protocol, and, thus, no influenza viruses can be 'considered exempt from the Nagoya Protocol's scope by virtue of Article 4.4'.⁷²

The implication of this is that, even if the PIP Framework is considered a specialized instrument under article 4(4), it does not follow that all influenza viruses with human pandemic potential automatically fall outside of the scope of the Nagoya Protocol – only the ones which member states actively choose to transfer to GISRS through the mechanisms created by the PIP Framework itself. The disapplication of the Nagoya Protocol for those virus samples would make very little sense, however, when the PIP Framework itself states that 'member states may also provide PIP biological materials directly to any other party or body on a bilateral basis provided that the same materials are provided on a priority basis to the WHO'.⁷³

An instrument would apply to a specific set of genetic resources and/or traditional knowledge associated with genetic resources, which would otherwise fall under the scope of the Nagoya Protocol

The CBD defines 'genetic resources' as 'genetic material of actual or potential value'.⁷⁴ The term 'genetic material' is defined as 'any material of plant, animal, microbial or other origin containing functional units of heredity'.⁷⁵ The Nagoya Protocol uses the same definitions for these terms as provided for in article 2 of the CBD.⁷⁶ Viruses, as protein capsules containing DNA or RNA ('genetic material') which are useful in scientific research and the development of vaccines and other products

71 Ibid 145.

72 Ibid 146.

73 Art 5(1)(4).

74 Art 2, CBD

75 Ibid.

76 Art 2, Nagoya Protocol.

(‘of actual or potential value’), do fit within the CBD’s (and therefore the Nagoya Protocol’s) definition of ‘genetic resources’.⁷⁷ If countries so choose, they can implement legislative, administrative and policy measures for accessing viral genetic resources, including provisions on prior informed consent and benefit-sharing as part of mutually agreed terms. The PIP Framework applies to a very narrow subset of the world’s known viruses, only ‘H5N1 and other influenza viruses with human pandemic potential’.⁷⁸ It does not apply to seasonal influenza viruses or other non-influenza pathogens.⁷⁹ The PIP Framework therefore applies to a specific set of genetic resources that would otherwise fall within the scope of the Nagoya Protocol, meeting the third criterion for a specialized instrument.

The third and fourth criteria from the Study address traditional knowledge (TK) associated with genetic resources, a uniquely challenging aspect of ABS under the CBD and Nagoya Protocol. The PIP Framework does not address the issue of TK associated with H5N1 and other influenza viruses with human pandemic potential. It may seem easy to discount the relevance of the TK of Indigenous Peoples and local communities associated with influenza viruses as it has not previously factored into the sharing of influenza virus samples through the WHO’s GISRS network of laboratories. But there is an increasing understanding of the importance of TK associated with genetic resources, including viruses.⁸⁰

The CBD asks contracting parties to ‘respect, preserve and maintain knowledge, innovations and practices’ of Indigenous Peoples and local communities, and ‘encourage[s] the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices’.⁸¹ The Nagoya Protocol goes much further, creating similar obligations for the use of TK ‘held or owned’⁸² by Indigenous Peoples and local communities associated with genetic resources as for the

77 Rourke (n 45 above) 79–89. Note also that if viruses did not fit within the scope of the CBD and Nagoya Protocol, there would not be a push from the WHO to have the PIP Framework included as a specialized instrument within this ABS regime. This in itself is evidence that the international community has decided to treat viruses as being subject to the ABS provisions of the CBD and Nagoya Protocol.

78 Art 3(1).

79 Art 3(2).

80 See Michelle Rourke, ‘When knowledge goes viral: assessing the possibility of virus-related traditional knowledge for access and benefit-sharing’ (2018) 21(5–6) *Journal of World Intellectual Property* 356.

81 Art 8(J).

82 Preamble, Nagoya Protocol.

genetic resources themselves. This includes prior informed consent for accessing TK⁸³ and the sharing of benefits on mutually agreed terms.⁸⁴

The definitions of both 'traditional knowledge' and 'Indigenous and local communities' in the CBD and Nagoya Protocol ABS regimes can be broadly interpreted⁸⁵ and, as with most of the contentious issues in this arena, have been left to individual parties to determine in their own legislative, administrative and policy measures. This means that there are many forms of TK that could be considered to be associated with viral genetic resources, including traditional burial practices that were associated with the spread of the Ebola virus during the West African Ebola epidemic in 2014–2015,⁸⁶ and in the context of influenza viruses 'it is possible that knowledge about traditional poultry or pig farming practices that provide insights about a strain of influenza virus (its transmission, virulence, or the susceptibility of particular animals) might qualify' as TK, the use of which may require prior informed consent and mutually agreed terms.⁸⁷

Traditional medicine has always been within the purview of the WHO, although it did not address the intellectual property aspects of traditional medicines until December 2000.⁸⁸ The Inter-regional Workshop on Intellectual Property Rights in the Context of Traditional Medicine 'produced recommendations regarding, *inter alia* ... the equitable sharing of benefits for commercial use of traditional medicine'.⁸⁹ Since 2000, the WHO has been working with the World Intellectual Property Organization (WIPO) to address 'the need to prevent misappropriation of health-related traditional knowledge' in the context of traditional medicine.⁹⁰ Thus, the WHO had been engaged in these issues at least a decade before the adoption of the

83 Arts 6(2) and 7.

84 Arts 5(2) and 7. Such measures are, of course, softened with the vague language that pervades the Nagoya Protocol: 'In accordance with domestic law, each Party shall take measures, as appropriate ...'. It is *not* clear whether not taking measures could also be considered 'appropriate' under the Nagoya Protocol.

85 Michelle Rourke, 'Who are "indigenous and local communities" and what is "traditional knowledge" for virus access and benefit-sharing? A textual analysis of the Convention on Biological Diversity and its Nagoya Protocol' (2018) 25(3) *Journal of Law and Medicine* 707–726.

86 Angellar Manguvo and Benford Mafuvadze, 'The impact of traditional and religious practices on the spread of Ebola in West Africa: time for a strategic shift' (2015) 22 (Suppl 1):9 *Pan African Medical Journal* 1–4.

87 Rourke (n 85 above).

88 Silke von Lewinski, *Indigenous Heritage and Intellectual Property: Genetic Resources, Traditional Knowledge and Folklore* (2nd edn, Kluwer Law International 2008) 45.

89 *Ibid.*

90 Dr Margaret Chan's Address at the WHO Congress on Traditional Medicine (WHO 2008).

PIP Framework. Given the primacy of TK in the Nagoya Protocol and the WHO's engagement on the issue of benefit-sharing related to the use of TK since 2000, it might be considered a major shortcoming of the PIP Framework that it does not even address the *possibility* of TK associated with influenza viruses with human pandemic potential.

An instrument would apply to specific uses of genetic resources and/or traditional knowledge associated with genetic resources, which would require a differentiated and hence specialized approach

As stated, prior to the adoption of the PIP Framework in 2011, the sharing of influenza viruses between the international scientific community and coordinated by the WHO was informal, but still highly structured and systematised. The basic structure of the GISN/GISRS has remained the same since 2011,⁹¹ but has since expanded and increased its global reach. The genetic properties of influenza viruses and the ongoing requirement to monitor their evolution (genetic drift) and the emergence of pandemic strains (through genetic shift) have dictated how the GISN/GISRS is structured. As a simplification, the GISRS laboratory network consists of 144 National Influenza Centers (NICs) which together 'process more than 3 million clinical specimens globally every year'⁹² and continuously feed information and virus samples into regional Collaborating Centers (CCs).⁹³ These, in turn, deliver information to the WHO and provide candidate vaccine virus isolates to vaccine manufacturers. This is the only global influenza laboratory network of its kind, and its continued operation is essential to determining which seasonal strains should be used to make annual influenza vaccinations and to detect the emergence of potentially pandemic strains. It is clear that the sharing of influenza viruses requires a different, specialized approach to that of other genetic resources, and even to that of other pathogens. But whether or not the PIP Framework can be said to constitute that specialized approach is rather more complicated.

Prior to 2011, the transfer of clinical samples and virus isolates from the NICs to the CCs occurred on an informal basis, and vaccine candidate virus isolates that originated from NICs were provided to vaccine manufacturers from CCs free of charge. The PIP Framework

91 The change of name from GISN to GISRS was symbolic. Youde notes that it 'helped to convey the message that a change had actually occurred as part of the [PIP Framework] negotiations': Youde (n 32 above) 130.

92 WHO (n 56 above) 7.

93 Alan Hay and John McCauley, 'The WHO global influenza surveillance and response system (GISRS): a future perspective' (2018) 12(5) *Influenza and Other Respiratory Viruses* 551. The GISRS network also includes Essential Regulatory Laboratories (ERLs).

had to be retrofitted to this 'pre-existing monopoly', where access to viruses was already controlled and tracked through the WHO's global network of laboratories.⁹⁴ The PIP Framework created a formal administrative structure around the transfer of human clinical specimens, wild-type and modified influenza viruses with human pandemic potential (now called 'PIP biological materials')⁹⁵ between WHO-affiliated laboratories (NICs and CCs) using the SMTA1, and from WHO laboratories to third parties, like vaccine manufacturers, using the SMTA2. Importantly, though, this formal administrative ABS structure only applies to the subset of virus samples that are identified as having human pandemic potential. And so, we would question why this specialized ABS approach is required for pandemic influenza viruses but not the many more seasonal influenza viruses that are shared in the same manner, through the same GISRS, but without the application of the PIP Framework.

Supportiveness

The remaining five criteria for specialized instruments refer to the extent to which the instrument under consideration is mutually supportive of the aims, objectives and functioning of the CBD and Nagoya Protocol. It is worth noting that 'mutual supportiveness' is a somewhat underdeveloped concept and '[l]ittle is known ... as to the exact legal nature and scope of the concept and its role in treaty interpretation and adjudication at the international and national level'.⁹⁶ Despite this, Wilke has commented that 'the two instruments [the PIP Framework and Nagoya Protocol] seem to be well equipped to form a working symbiosis'.⁹⁷ The extent to which this apparent symbiosis is sufficient to meet the criteria for specialized instruments under the 2018 Study will be considered below.

Consistency with biodiversity conservation and sustainable use objectives

When Indonesia withheld its influenza virus samples from the WHO in 2006/2007, many commentators highlighted the incompatibility of applying the sovereignty provisions of the CBD, an environmental conservation treaty, with public health objectives which include the

94 Deborah Scott and Dominic Berry, 'Genetic resources in the age of the Nagoya Protocol and gene/genome synthesis' (Report and Analysis of an Interdisciplinary Workshop 18 November 2016) 20.

95 Art 4(1).

96 Wilke, 'A healthy look at the Nagoya Protocol' (n 4 above) 137.

97 Ibid 146.

eradication of disease agents like influenza viruses.⁹⁸ Fidler, for example, stated that 'interpreting the CBD to apply to pathogenic viruses may be contrary to the CBD's purpose',⁹⁹ highlighting (correctly) that 'avian influenza viruses ... are not the kind of biological and genetic resources that the CBD sought to protect and regulate through the principles of sovereignty, prior informed consent, and mutual benefits from access and exploitation'.¹⁰⁰ But arguments of this nature¹⁰¹ tend to take into account only the first two objectives of the CBD: 'the conservation of biological diversity' and 'the sustainable use of its components'.¹⁰² Indonesia's argument and the ensuing PIP Framework undoubtedly fit within the third objective of the CBD: 'the fair and equitable sharing of the benefits arising out of the utilization of genetic resources'.¹⁰³ It is this third objective around which the entire Nagoya Protocol is built.¹⁰⁴

The text of the CBD does not *explicitly* link its third objective of 'fair and equitable sharing of the benefits arising out of the utilization of genetic resources' with achieving the first two objectives of biodiversity conservation and sustainable use. However, the Nagoya Protocol's objective is to achieve:

... fair and equitable sharing of the benefits arising from the utilisation of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, *thereby contributing to the conservation of biological diversity and the sustainable use of its components.*¹⁰⁵ (emphasis added)

The PIP Framework's objective is:

... to improve pandemic influenza preparedness and response, and strengthen the protection against the pandemic influenza by improving and strengthening the [GISRS], with the objective of a fair, transparent,

98 Fidler (n 43 above); Kelly Lee and David Fidler, 'Avian and pandemic influenza: progress and problems with global health governance' (2007) 2(3) *Global Public Health* 215–234.

99 Fidler (n 43 above) 90.

100 *Ibid.*

101 Noting that Fidler's argument is, of course, much more nuanced than what has been presented here.

102 Art 1. See also section on 'Contribution to sustainable development, as reflected in internationally agreed goals', page 437 below.

103 CBD Art 1. This objective continues: 'including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and technologies, and by appropriate funding'.

104 *Ibid.* 1.

105 *Ibid.*

equitable, efficient, effective system for, on an equal footing: (i) the sharing of H5N1 and other influenza viruses with human pandemic potential; and (ii) access to vaccines and sharing of other benefits.¹⁰⁶

Clearly, the overarching objectives of equity and fairness in the sharing of benefits associated with the use of genetic resources in the CBD, Nagoya Protocol and PIP Framework align. Notwithstanding the fact that isolating viruses from their hosts could be considered an act of *ex situ* biodiversity conservation, it cannot be said that the PIP Framework actively contributes to realising the biodiversity conservation and sustainable use objectives envisaged by the CBD and explicitly tied to ABS in the Nagoya Protocol. Nevertheless, we feel that not meeting this criterion is not essential to recognition as a specialized ABS instrument, so the relevant question here is to what extent the PIP Framework actually contributes to the fairness and equity objectives of the CBD and Nagoya Protocol, addressed below.

Fairness and equity in the sharing of benefits

The PIP Framework uses the term 'benefits' to refer to both the allocation of tangible diagnostics, vaccines and antivirals provided for specifically under the new PIP Framework and its SMTA2s,¹⁰⁷ and to those benefits that were already made available through the GISN (now GISRS). These include having the WHO coordinate pandemic preparedness and response,¹⁰⁸ and providing 'risk assessment and early warning information ... to all countries'.¹⁰⁹ Throughout the negotiation of the PIP Framework, it was clear that the countries demanding a fair and equitable share of the benefits arising from the utilisation of their viruses were referring to a fair share of the tangible diagnostics, vaccines and antivirals that had previously been denied them.¹¹⁰ The value of the PIP Framework for these member states is that the pharmaceutical companies that were previously profiting from the use of their genetic resources were 'now requested to share the *actual benefits* of commercial research – be they in the form of vaccines, medical treatment, relevant production licences or similar means – on the basis of material transfer agreements'¹¹¹ (emphasis added).

The PIP Framework generates new benefits (as in, benefits that were not generated by the GISN prior to the existence of the PIP Framework) through two mechanisms: SMTA2s and an annual subscription payment from pharmaceutical companies using the GISRS, known as

106 Art 2.

107 Art 5(4)(2) and annex 2.

108 Art 6.

109 Arts 6(0)(2)(i) and 6(2).

110 WHO (n 37 above).

111 Wilke, 'The WHO's Pandemic Preparedness Framework' (n 4 above) 319.

Partnership Contributions.¹¹² The SMTA2 is signed by third parties that receive PIP biological materials from the GISRS, committing to provide benefits to the WHO like vaccines and antivirals in accordance with their abilities. These obligations are only enacted in the event of an influenza pandemic, when the WHO will distribute these benefits 'to developing countries, particularly affected countries, according to public health risk and needs'.¹¹³

The SMTA2 was a highly innovative mechanism under international law as it took the PIP Framework's provisions from its (soft law) WHA resolution into the realm of private law, where non-state actors (including pharmaceutical companies) could be regulated. This was seen as a step towards fair and equitable benefit sharing as it reduced the power dynamics between the (often) developing countries negotiating mutually agreed ABS terms with multinationals.¹¹⁴ However, since concluded SMTA2s between vaccine manufacturers and the WHO have become publicly available, a more critical perspective has emerged doubting that the SMTA2s will deliver tangible benefits during an influenza pandemic.¹¹⁵

Since the adoption of the PIP Framework in 2011, 13 vaccine and antiviral manufacturers have entered into SMTA2s. The WHO has reported that these agreements would provide the agency with 400 million doses of pandemic influenza vaccine, 10 million treatment courses of antiviral drugs, 250,000 diagnostic kits, and 25 million syringes in the event of an influenza pandemic. The PIP Framework states that one-third of this stockpile 'will be for use in affected countries, according to public health risk and need, to assist in containing the first outbreak or outbreaks of an emerging pandemic';¹¹⁶ and two-thirds 'will be for distribution, once a pandemic begins, to developing countries that have no or inadequate access to H5N1 influenza vaccines, on a per capita basis, with use to be determined by those countries'.¹¹⁷

It is important to note that the stockpile of 400 million doses of pandemic influenza vaccine is, by necessity, a virtual stockpile. The genetic drift of the virus is what necessitates the selection of

112 WHO, 'Pandemic Influenza Preparedness (PIP) Framework: Partnership Contribution (PC) Preparedness High-Level Implementation Plan II 2018–2023' Revised Version (WHO 2019) 3.

113 Art 6(0)(2)(iii), PIP Framework.

114 Wilke, 'The WHO's Pandemic Preparedness Framework' (n 4 above) 329; Nicole Jefferies, 'Levelling the playing field? Sharing of influenza viruses and access to vaccines and other benefits' (2012) 20(1) *Journal of Law and Medicine* 59.

115 Mark Eccleston-Turner, 'The Pandemic Influenza Preparedness Framework: a viable procurement option for developing states?' 17(4) *Medical Law International* (2017); Rourke (n 3 above).

116 Art 6(9)(2) (i).

117 Art 6(9)(2) (ii).

new seasonal influenza vaccine strains each year, and genetic shifts make it impossible to determine what vaccine should be stockpiled in preparation for a pandemic. Thus, the PIP Framework's vaccine stockpile is on paper until such time as those pharmaceutical manufacturers that are party to the SMTA2s start producing pandemic vaccines and those SMTA2s are operationalised. Using the projections for the number of promised vaccine doses in the virtual stockpile, it is clear that it is unlikely to be sufficient to meet demand in developing countries during an influenza pandemic.¹¹⁸ Indeed, at the point at which a vaccine becomes available during a pandemic (approximately six to seven months into the outbreak assuming no production problems),¹¹⁹ demand in affected and developing countries that have no or inadequate access will far exceed the doses available through the PIP Framework's virtual stockpile.

Our key concern is that these benefits may not even materialise at all. In the first instance, the contractual obligations contained in the concluded SMTA2s between WHO and vaccine manufacturers may lack legal force.¹²⁰ One SMTA2 made publicly available by the WHO even included clauses that indemnified the manufacturer for almost every foreseeable difficulty to uphold its contractual obligations, including an influenza pandemic.¹²¹ If the SMTA2s are upheld and manufacturers do donate a portion of their real-time vaccine production (this is just one example of the SMTA2 benefit-sharing options), there are still barriers to having those vaccines delivered to the WHO as promised:¹²²

... concern has been expressed by the industry that during an influenza pandemic, member states with domestic [pandemic influenza vaccine] production within their territory would place restrictions on exports of [pandemic influenza vaccine] that have been committed to the PIP stockpile, until domestic demand had been fulfilled.¹²³

Assuming, however, that the promised benefits will be available to the WHO, the PIP Framework provides no further guidance on how they are to be shared, other than to say:

As regards the benefits outlined in this Framework, WHO should pay particular attention to policies and practices that promote the fair, equitable and transparent allocation of scarce medical resources

118 Eccleston-Turner (n 115 above).

119 WHO, 'Pandemic influenza vaccine manufacturing process and timeline: Pandemic (H1N1) 2009' Briefing Note 7, 6 August 2009.

120 Rourke (n 3 above) 100–103.

121 Ibid 102.

122 Ibid; Eccleston-Turner (n 115 above); Mark Eccleston-Turner, Alexandra Phelan and Rebecca Katz, 'Preparing for the next pandemic: the WHO's Global Influenza Strategy' (2019) 381(23) *New England Journal of Medicine* 2192.

123 Eccleston-Turner (n 115 above).

(including, but not limited to, vaccines, antivirals and diagnostic materials) during pandemics based on public health risk and needs, including the epidemiology of the pandemic.¹²⁴

There is no further guidance about how tangible benefits should be apportioned during a pandemic beyond the virtual stockpile distribution ratio of one-third for affected and two-thirds for developing countries detailed above.¹²⁵ It is important to note that diagnostics, vaccines and antiviral medicines promised under the SMTA2s will be provided to the WHO for onward transfer to affected or developing countries in real-time. This means that the WHO will have to make decisions about whether the first shipment is to go to affected country A or affected country B, and on what basis. The PIP Framework provides inadequate guidance on how this is to be determined, and it is therefore difficult to ascertain whether the PIP Framework does indeed meet the criteria of fair and equitable sharing for those benefits promised under the SMTA2 mechanism. It is an unfortunate fact that we will not be able to judge the equity and fairness criteria until such time as there is an influenza pandemic, and all of the PIP Framework's benefit-sharing provisions come into play.

The second mechanism through which the PIP Framework generates benefits is the annual Partnership Contribution. This is essentially an annual subscription payment to the WHO by any '[i]nfluenza vaccine, diagnostic and pharmaceutical manufacturers' that make use of the GISRS.¹²⁶ Unlike the benefit-sharing that occurs under the SMTA2s, benefit-sharing through Partnership Contributions is not contingent upon an active influenza pandemic. The annual Partnership Contributions are supposed to total the equivalent of half of the annual running costs of the GISRS and are used to improve pandemic preparedness and response.¹²⁷ The Partnership Contribution from vaccine, diagnostic and antiviral manufacturers generates USD28 million per year for the WHO, of which 10 per cent is used to fund the PIP Framework's governing body (the PIP Secretariat), and 'of the remainder, 30% are set aside for response during an influenza pandemic and 70% of funds are allocated for preparedness'.¹²⁸ As of the most recent Partnership Contribution report, the vast majority of that preparedness funding had been allocated to 'Laboratory and Surveillance Capacity Building',¹²⁹ outstripping the funding allocated

124 Art 6(1).

125 Art 6(9)(2).

126 Art 6(14)(3).

127 Ibid.

128 WHO, 'Pandemic Influenza Preparedness Framework Progress Report 1 January 2018–30 June 2019' (2019) vi.

129 Ibid 6.

to the categories of Regulatory Capacity Building, Risk Communications and Community Engagement, Burden of Disease, Influenza Pandemic Preparedness Planning and Planning for Deployment combined.¹³⁰ The funding for Laboratory and Surveillance Capacity Building, as the name suggests, is aimed at strengthening the core activities of the GISRS. Capacity-building activities under this banner include '[s]trengthen[ing] data and information sharing from national to regional and global platforms and improv[ing] data management systems' and '[f]acilitat[ing] influenza sample shipment to GISRS by providing necessary consumables and train[ing] NIC staff to select and ship quality samples'.¹³¹

We are not suggesting for a moment that these are not vital activities, and we fully support the strengthening of the GISRS. However, from an ABS point of view (and this is, of course, the purpose of this exercise), the benefits provided through the Partnership Contributions (increasing lab and surveillance capacity, NIC training and community engagement) are not the type of benefits that developing countries had in mind as the PIP Framework was being negotiated. The access part of the transaction was supposed to be about member states providing their sovereign viruses to the WHO (GISRS), and the benefit-sharing portion was supposed to be about the fair and equitable distribution of diagnostics, vaccines and antivirals. The GISRS capacity-building activities funded by the Partnership Contributions can ultimately be seen as strengthening the access side of the ABS transaction.¹³²

Because the tangible benefits of the PIP Framework cannot 'be provided in a preferential manner to the country from which the virus had originated, but rather as a pooled benefits system based on public health risk and need (aimed at developing countries)',¹³³ there is no direct link between the access and the benefit-sharing side of the PIP Framework's ABS transaction. This would not necessarily be a bad thing if all resources (virus samples and benefits) were treated as common pools.¹³⁴ But under the PIP Framework, the viruses and associated data contributed to GISRS by WHO member states continue to be treated as global public goods¹³⁵ (and strengthening the GISRS increases the value of those public goods), but the fair and equitable sharing of diagnostics, vaccines and antivirals is in no way guaranteed

130 Ibid.

131 Ibid.

132 See also Rourke (n 3 above).

133 Ibid.

134 See Wilke, 'The WHO's Pandemic Preparedness Framework' (n 4 above).

135 Youde (n 32 above) 115.

by the PIP Framework, meaning that these continue to be treated as private goods and are likely to be distributed accordingly.¹³⁶

Legal certainty with respect to access to genetic resources or traditional knowledge and to benefit-sharing

The PIP Framework applies only to 'PIP biological materials', which are defined by the PIP Framework as 'human clinical specimens, virus isolates of wild type ... influenza viruses with human pandemic potential; and modified viruses ... with human pandemic potential'.¹³⁷ However, no further definition is given as to what influenza virus subtypes constitute having 'human pandemic potential' for the meaning of the PIP Framework. It therefore falls to individual NIC laboratories to make a determination if the virus samples they hold ought to be shared with the GISRS under the terms of the PIP Framework. Often NICs do not have the ability to conduct the testing required to determine whether a virus sample has human pandemic potential, testing that occurs at the regional CCs. Therefore, samples are often transferred from the NICs to the CCs before it is clear whether the PIP Framework even applies to those samples.¹³⁸

There is also a level of legal uncertainty with respect to third-party transfers of PIP biological materials. The host country NICs transfer virus samples to regional CCs under the SMTA1, and the act of providing samples constitutes consent to the onward transfer of their PIP biological materials to other GISRS laboratories.¹³⁹ It also constitutes consent for the CCs to transfer PIP biological materials to third-parties under an SMTA2.¹⁴⁰ An SMTA2 authorises the transfer of the PIP biological materials from GISRS to parties that sit outside of the GISRS network, including academic laboratories and research institutes, as well as diagnostic and vaccine manufacturers.¹⁴¹ As already outlined, it is through the SMTA2 that these third-parties agree to provide benefits in return for access to PIP biological materials. Despite being a standardised agreement, the SMTA2s can take a long time to negotiate. Accordingly, the WHO has deemed it sufficient to provide PIP biological materials to third parties using only a shipping notice that contains a weak and uncertain '[a]greement to conclude' an SMTA in some undefined future.¹⁴² This shipping notice states that 'by

136 See also Eccleston-Turner (n 115 above).

137 Art 4(1).

138 See Rourke (n 3 above) 100.

139 Art 5(4)(1) and annex 1.

140 Art 5(4)(2) and annex 2.

141 Ibid.

142 WHO, 'PIPBM Shipping Notice' (1 October 2019).

receiving these materials you are signalling your intention to be bound by the terms of a future SMTA2'. The legal effect of this is uncertain, but clearly 'vague references to unknown terms cannot form the basis of a contract'.¹⁴³ Significant elements of the SMTA2 are negotiable, not just for the benefit-sharing commitments manufacturers agree to, but also provisions on liability and indemnity, jurisdiction and shipping arrangements. As such, it is reasonable to assume that third-party recipients may not be able to conclude an SMTA2 with the WHO on mutually agreed terms, or in good time. It is unclear what this would mean in terms of tangible benefit-sharing in the event of a pandemic, or what may eventuate if the third party and the WHO cannot reach an agreement that forms the basis of an SMTA2 and that third party had already used the PIP biological materials before concluding an SMTA2. The lack of specificity and binding nature of the terms of the WHO's shipping notice for PIP biological materials cannot be said to provide any legal certainty over transfers of PIP biological materials to third parties without an SMTA2. Given the extant legal uncertainty in both the access and the benefit-sharing sides of the ABS transaction under the PIP Framework, it fails to meet this criterion of the specialized instrument Study.

Contribution to sustainable development, as reflected in internationally agreed goals

The Study highlights 'the explicit link established between benefit-sharing and the other two objectives of the CBD – *conservation and sustainable use*' (emphasis in original) and that ABS 'is not to be pursued in isolation from the broader framework established by the CBD'.¹⁴⁴ It is hard to interpret the ABS provisions of the PIP Framework, or indeed any part of the PIP Framework, as contributing to 'inter alia, the selection and management of protected areas and species, the restoration of degraded ecosystems and the protection and promotion of traditional knowledge',¹⁴⁵ again, notwithstanding the fact that the isolation of wild-type influenza viruses and their storage in laboratory freezers might be considered species conservation. The Preamble of the Nagoya Protocol presents a broad conception of sustainable development, which includes the 'contribution to sustainable development made by technology transfer and cooperation to build research and innovation capacities for adding value to genetic resources in developing countries' and the 'potential role' of ABS to

143 Aaron Perzanowski and Jason Schultz, *The End of Ownership: Personal Property in the Digital Economy* (MIT Press 2016) 68.

144 CBD (n 4) 8.

145 Ibid.

contribute 'to achieving the Millennium Development Goals'.¹⁴⁶ The Millennium Development Goals were succeeded by the Sustainable Development Goals (SDGs), adopted by all UN member states in 2015.¹⁴⁷ For the PIP Framework, the SDG 3 to ensure healthy lives and promote well-being for all at all ages is particularly relevant.¹⁴⁸

The SDG 3 targets include 'access to safe, effective, quality and affordable essential medicines and vaccines for all', 'support[ing] the research and development of vaccines and medicines' and 'strengthen[ing] the capacity of all countries, in particular developing countries, for early warning, risk reduction and management of national and global health risks'.¹⁴⁹ While we have concerns that the PIP Framework will be unable to deliver the promised vaccines during an influenza pandemic, it is clear that the PIP Framework's Partnership Contributions that go towards strengthening GISRS capacity undoubtedly contribute to sustainable development under SDG 3. Thus, the PIP Framework could be said to meet this criterion of the Study.

Other general principles of law including good faith, effectiveness and legitimate expectations

It is possible to separate out the access side of the PIP Framework and the benefit-sharing side when determining whether it meets the general principle of effectiveness. While the non-binding PIP Framework may have worked to codify virus-sharing norms, there is nothing in the PIP Framework that can compel countries to share their influenza viruses with the GISRS, or avert a similar crisis to the one that was the very impetus for the PIP Framework.¹⁵⁰ Thus, the PIP Framework is only effective as an access mechanism in as much as countries providing virus samples trust that the benefit-sharing mechanisms will be effective.

The effectiveness of the PIP Framework's benefit-sharing mechanisms is difficult to ascertain, as the full complement of benefit-sharing options has not been put to the test during an influenza pandemic. Unfortunately, the PIP Framework 'has not sufficiently engaged with, or found appropriate solutions to, the current market-

146 Preamble.

147 [United Nations Development Programme \(UNDP\), SDGs.](#)

148 Michala Hegermann-Lindencrone et al, 'Innovative Pandemic Influenza Preparedness framework paves the way for sustainable improvements to pandemic preparedness' (2018) 4(1) Public Health Panorama 79.

149 UNDP, [SDG 3: Ensure healthy lives and promote well-being for all at all ages.](#)

150 'Little that triggered or transpired during [the 2006/2007 virus sharing] controversy would therefore violate the framework that supposedly resolves it': Smith (n 43 above).

based structural hurdles that prevent equitable access to vaccines, namely limited overall global production capacity, the prevalence of [advanced purchase agreements] and the need for more private sector investment¹⁵¹ and is highly unlikely to be an efficient or effective benefit-sharing tool in the event of a pandemic.

Another challenge affecting the effectiveness of the PIP Framework, both in terms of enabling access and for the sharing of benefits, is synthetic biology and the move toward using influenza genetic sequence data for developing vaccines. In 2016, the PIP Framework Review Group noted that genetic sequence data (GSD) could in some cases be used instead of physical virus samples during pandemic risk assessment and for vaccine development,¹⁵² and the technical developments are such that this move away from using physical viral samples and instead using GSD is expected to grow.¹⁵³ This means that third-party users of 'dematerialised' PIP biological materials can avoid entering into an SMTA2 with the WHO despite still benefiting from the contribution of member states and the outputs of the GISRS.¹⁵⁴ The WHO has stated that, while there is no obligation to enter into an SMTA2, any manufacturers that use 'GSD produced by the GISRS ... are expected to contribute an annual Partnership Contribution payment'.¹⁵⁵ What this fails to appreciate, however, is that it is usually possible to access this GSD free of charge on any number of publicly accessible databases, often without any way of determining who has accessed that data (that is, you do not need to pay a Partnership Contribution to see or use GSD from influenza viruses with human pandemic potential).

While the PIP Framework recognises 'that in some instances the publication of [GSD] has been considered sensitive by the country providing the virus',¹⁵⁶ it still encourages all member states to share GSD,¹⁵⁷ despite the fact that it is not included in the PIP Framework's ABS regime. This loophole has been acknowledged by the WHO since 2013, and in 2014 the PIP Framework's Technical

151 Adam Kamradt-Scott and Kelly Lee, 'The 2011 Pandemic Influenza Preparedness Framework: global health secured or a missed opportunity?' (2011) 59(4) *Political Studies* 831, 844–845.

152 WHO, 'Review of the Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits: Report of the 2016 Pandemic Influenza Preparedness Framework Review Group' (18 November 2016).

153 See WHO, 'Fact sheet: new technologies using genetic sequence data', 4 April 2018.

154 WHO, *Approaches to Seasonal Influenza and Genetic Sequence Data under the PIP Framework*, 14 December 2018, 17.

155 WHO (n 56 above) 18.

156 Art 5(2)(3).

157 Art 5(2)(1).

Expert Working Group convened to assess the scientific, technical, operational and intellectual property implications of using GSD instead of physical viruses for research and vaccination production, and how the use of this data could be monitored. The 2016 meeting of the PIP Framework's Technical Working Group on GSD proposed amending the PIP Framework to include GSD within the definition of PIP biological materials and therefore include GSD utilisation in the ABS arrangements of the PIP Framework.¹⁵⁸ However, none of these proposals has come to pass, and to date no amendments or conclusions have been reached to minimise the impact that free and open access to influenza GSD will have on the sharing of physical influenza samples under the PIP Framework.

On the point of general principles of law, the extent to which dispute resolution under the PIP Framework aligns with principles of good faith, justice and fairness is also questionable. The PIP Framework does provide for dispute resolution for member states providing PIP biological materials under the SMTA1.¹⁵⁹ In the first instance, parties are to attempt to settle the dispute via negotiation. However, in the event of this failing, 'one of the parties concerned may refer the dispute to the Director-General, who may seek advice of the Advisory Group with a view to settling it'.¹⁶⁰ This seems logical if the dispute to be resolved is between the party providing PIP biological materials and the party using those materials to generate benefits to be shared with the provider. However, what this dispute resolution mechanism fails to acknowledge is that there is no agreement between the provider and user parties under the PIP Framework. The SMTA1 is an agreement between the member states providing PIP biological materials and the WHO, and the SMTA2 is an agreement between WHO and a third-party user. This means that the WHO is a party to both the SMTA1 and the SMTA2, and there is no direct link between member states and third parties like vaccine manufacturers. It seems rather bizarre to have designed a dispute resolution mechanism which is to be adjudicated upon by one of the parties to the agreement under dispute, nor does it seem like a system that would meet legitimate expectations of fair and effective dispute resolution.

158 This was also outlined as a potential option in WHO (n 56 above) 30; GISAID (n 56 above) 24–26.

159 Annex 1, art 7.

160 Annex 1, art 7(2).

THE PIP FRAMEWORK AND LEGAL CERTAINTY IN ABS ARRANGEMENTS

The previous section examined aspects of the PIP Framework against the nine criteria for specialized ABS instruments outlined in the 2018 Study for the Subsidiary Body on Implementation to the CBD. Despite some shortcomings, including the fact that the PIP Framework does not consider virus-related traditional knowledge of Indigenous Peoples and local communities, we are satisfied that the PIP Framework likely meets the four criteria for specialization. However, the PIP Framework has major shortcomings when it comes to realising three of the five criteria on supportiveness: fairness and equity in benefit-sharing, creating legal certainty for ABS and the general legal principles of effectiveness and legitimate expectations, which all link back to legal certainty.

Despite applying only to influenza viruses with human pandemic potential, the PIP Framework reinforces the norm of sharing both seasonal and pandemic influenza viruses. This is because countries often do not know whether the samples they are providing to the GISRS are classified as seasonal or pandemic influenza viruses until the analysis occurs within the GISRS. This means that, for whatever legal certainty the PIP Framework might provide for the transfer of pandemic influenza viruses to third parties outside of GISRS laboratories, there is no equivalent certainty for the seasonal influenza viruses that have already been contributed to the GISRS by member states. These are still subject to benefit-sharing obligations under the CBD and the CBD/Nagoya Protocol ABS regimes, but the member states have lost any ability to monitor or functionally control the use of seasonal influenza virus samples that they have already provided to the GISRS. Indeed, vaccine manufacturers often obtain their seasonal candidate vaccine virus strains from the GISRS, and there has already been confusion about whether the PIP Framework or the Nagoya Protocol should govern such transfers.¹⁶¹ Countries that routinely contribute viruses to the GISRS guarantee the WHO access to their seasonal *and* pandemic influenza viruses but could be doing so on the promise of benefits that are linked solely to the pandemic influenza viruses. Put simply: countries are generally expected to provide access to all influenza viruses but are promised benefits in return for just a minority of them. Whether or not those benefits will be forthcoming is

161 WHO (n 56 above) 30. Given the PIP Framework is applicable only to those pandemic influenza viruses shared with the GISRS, the Nagoya Protocol is the instrument that governs transfers of seasonal influenza candidate vaccine strains to third parties. This means that those countries can negotiate prior informed consent and mutually agreed terms on a bilateral, case-by-case basis.

another level of legal uncertainty that sovereign nations must assume when providing influenza viruses under the PIP Framework.

The issue of GSD presents yet another access-related problem that undermines the ability of the WHO to secure benefits through the PIP Framework and therefore any legitimate expectations of receiving such benefits by those providing samples to the GISRS. As outlined above, GSD is not included in the definition of PIP biological materials, and synthetic biology technology has developed such that many uses of influenza viruses by pharmaceutical companies and other third-party users no longer necessitate access to physical samples.¹⁶² The WHO has claimed that users of GSD generated through the GISRS would still be expected to make an annual Partnership Contribution payment,¹⁶³ but this completely disregards the fact that similar (or indeed identical) GSD is usually available through open access databases like GenBank, and that there is no reliable method for tracking or tracing the use of such data. While GSD is often framed as an emerging issue, this has been on the radar of the WHO since the PIP Framework's inception,¹⁶⁴ and, as yet, there has been no decision on how to deal with this loophole despite it severely undermining the legal clarity that the PIP Framework is supposed to provide for those countries contributing physical samples to the GISRS.

As an ABS instrument, the PIP Framework does not adequately define which actions constitute access and which it considers benefit-sharing. For instance, the provision of candidate vaccine viruses to influenza vaccine manufacturers should be considered providing access to PIP biological materials. However, the PIP Framework addresses this under article 6 on benefit-sharing. That is, the PIP Framework treats the provision of some PIP biological materials to vaccine manufacturers as benefit-sharing. These are clearly not the benefits for which the PIP Framework was intended to ensure fair and just distribution. Any future specialized instruments would do well to indicate precisely what actions constitute access and which constitute benefit-sharing for the purposes of providing legal clarity.

The PIP Framework does specify a limited number of benefits which are directly tied to providing PIP biological materials: the

162 Michelle Rourke et al, 'Policy opportunities to enhance sharing for pandemic research' (2020) 368(6492) *Science* 716; Michelle Rourke, Alexandra Phelan and Charles Lawson, 'Access and benefit-sharing following the synthesis of horsepox virus' (2020) 35(8) *Nature Biotechnology* 539

163 WHO (n 56 above) 18.

164 Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccine and Other Benefits, Sharing of Influenza Viruses and Access to Vaccines and Other Benefits: Interdisciplinary Working Group on Pandemic Influenza Preparedness, Report by the Director-General, A/PIP/IGM/4.

active participation of scientists from originating laboratories in scientific projects associated with those materials;¹⁶⁵ access to the genetic sequence data and analyses derived from those materials;¹⁶⁶ and acknowledgment of 'the contribution of collaborators' in downstream 'presentations and publications'.¹⁶⁷ But many countries are contributing to the GISRS on the promise of tangible benefits to be delivered in the event of an influenza pandemic: those diagnostics, antiviral medications and vaccines that can help the worst-hit countries cope with the crisis. The SMTA2s – the mechanism used by the PIP Framework to generate these tangible benefits for distribution by the WHO in the event of a pandemic – are as yet untested and appear unlikely to deliver the quantum of benefits required to adequately respond to an influenza pandemic, or even those envisaged in the PIP Framework itself. Furthermore, there is little legal certainty as to how these tangible benefits will be distributed as the PIP Framework simply states that the WHO will distribute benefits 'according to public health risk and needs'.¹⁶⁸ This is assuming that these tangible benefits are indeed available for distribution, which depends in large part on whether the PIP Framework's SMTA2s are a viable legal instrument for securing such benefits.¹⁶⁹

The point of benefit-sharing for an instrument designed to create a common pool of resources, like that created by the PIP Framework,¹⁷⁰ is that it incentivises countries to provide access to their sovereign genetic resources. Access and benefit-sharing is a transactional mechanism; a *quid pro quo*. For now, physical virus samples are required to manufacture vaccines. The bilateral version of this transaction is envisaged as the vaccine manufacturers willing to pay (share benefits with) the country that can provide access to the raw materials required to make their product. Countries can choose to regulate this transaction through their own legislative, administrative or policy measures, or can choose to have the transaction facilitated through the WHO under the PIP Framework. If countries determine that the sharing of benefits from the PIP Framework's common pool is not fair and equitable or will not be forthcoming, then they are unlikely to continue to provide access to the viruses. Thus, there is an inherent tension built into the way that the PIP Framework proposes to allocate benefits. If the WHO provides PIP Framework benefits based solely on public health needs and irrespective of whether a particular country has

165 Annex 1, art 5(2).

166 Art 5(2)(1).

167 Annex 1, art 5(3).

168 Art 6(0)(2)(iii).

169 See Rourke (n 3 above); Eccleston-Turner (n 115 above).

170 See Wilke, 'The WHO's Pandemic Preparedness Framework' (n 4 above) 325.

contributed virus samples to the GISRS, then there is no incentive for any individual country to provide its viruses. The GISRS will continue to operate without such countries' contributions, and they still stand to receive benefits if warranted on the basis of public health needs.¹⁷¹ But, if the WHO decides that it must prioritise the delivery of benefits to countries that have continually provided viruses to the GISRS in order to keep the PIP Framework's incentive structure strong, it has now entered dangerous territory, acting on political expediency rather than on the basis of public health alone, and therefore outside of the PIP Framework's expressed provisions on benefits distribution. This highlights the folly of using the ABS transaction as a means of securing access to resources that are absolutely essential to global health security. If the PIP Framework does not get benefit-sharing right, then the WHO risks continued access to the influenza viruses (seasonal and pandemic) that the world needs to monitor and respond to seasonal influenza, detect and alert the world to a potential pandemic, and ensure the samples required by vaccine manufacturers to help respond to that pandemic are available immediately.

The Study's interest in legal certainty (criterion 7) referred to 'legal certainty with respect to access to genetic resources ... and to benefit-sharing'. We could refer to this as internal certainty (the interaction between the parties within the PIP Framework). However, there is further legal uncertainty that must be addressed about the PIP Framework's relationship with the Nagoya Protocol (and the CBD) if it were to be recognised as a specialized instrument, or, external certainty (interactions with other international instruments and norms). In addressing the PIP Framework's relationship to the Nagoya Protocol, the 2016 PIP Framework Review Group stated that the recognition of the PIP Framework as a specialized instrument:

... should facilitate fulfilment of the PIP Framework's access and benefit sharing objectives by ensuring that all countries would handle IVPP [influenza viruses with human pandemic potential] in the same way. IVPP access and sharing would be covered for Nagoya Protocol purposes by the PIP Framework, and therefore not require bilateral agreements on a case-by-case basis.¹⁷²

This sentiment was repeated in a 2017 WHO study into the public health implications of the Nagoya Protocol which stated that recognition of the PIP Framework as a specialized instrument:

... would mean that the Nagoya Protocol's requirements for case-by-case Prior Informed Consent and Mutually Agreed Terms would not

171 This is analogous to the 'Tragedy of the Commons': Garrett Hardin, 'The Tragedy of the Commons' (1968) 162(3859) *Science* 1243.

172 WHO (n 18 above) 96.

apply with respect to influenza viruses with human pandemic potential. This could promote 'legal certainty' with respect to such pathogens, strengthening the mechanisms of the PIP Framework.¹⁷³

The PIP Framework Review Group and PIP Secretariat¹⁷⁴ appear to be working on the assumption that recognition as a specialized instrument would mean that 'all countries would handle IVPP in the same way', that is, the PIP Framework way.¹⁷⁵ The assumption of external legal certainty upon recognition as a specialized instrument is inaccurate. The PIP Framework 'only functions as a specialized ABS instrument for influenza viruses where transfers are covered by the Framework's binding contract clauses'.¹⁷⁶ Wilke states that 'the [PIP] Framework may only partially be considered a specialized ABS instrument within the meaning of the [Nagoya] Protocol',¹⁷⁷ because it does not include *all* pandemic influenza viruses with human pandemic potential, just the ones that countries have chosen to share under the terms of the PIP Framework's SMTAs. There are still influenza viruses with human pandemic potential shared bilaterally outside of the GISRS. That means that 'the Nagoya Protocol must remain applicable in the background',¹⁷⁸ and, thus, not all influenza viruses with human pandemic potential can be 'considered exempt from the Nagoya Protocol's scope by virtue of Article 4.4'.¹⁷⁹ Thus, recognition of the PIP Framework as a specialized instrument achieves nothing in the way of clarifying the legal confusion surrounding the application of the PIP Framework; confusion that has already caused delays in accessing influenza viruses for vaccine production.¹⁸⁰

CONCLUSION

Article 4 of the Nagoya Protocol affords parties the latitude needed to design and implement specialized ABS arrangements for particular subsets of genetic resources that are ill-suited to the default bilateral measures envisaged in the CBD and Nagoya Protocol. There have been calls to have the PIP Framework recognised as a specialized instrument

173 WHO, *Implementation of the Nagoya Protocol and Pathogen Sharing: Public Health Implications* (WHO 2017) 23.

174 National Academies of Sciences, Engineering, and Medicine, *Exploring Lessons Learned from a Century of Outbreaks: Readiness for 2030: Proceedings of a Workshop* (2019) 96.

175 WHO (n 18) 22–23.

176 Wilke, 'A healthy look at the Nagoya Protocol' (n 4 above) 126.

177 *Ibid* 126.

178 *Ibid* 145.

179 *Ibid* 146.

180 WHO (n 56 above) 30.

with the assertion that doing so would clarify the applicability of the PIP Framework in relation to the CBD and Nagoya Protocol and therefore the appropriate global ABS arrangements for influenza viruses.¹⁸¹ The analysis above indicates that recognition as a specialized instrument would not result in the 'disapplication'¹⁸² of the CBD/Nagoya Protocol for all influenza viruses with human pandemic potential: only for those pandemic influenza virus samples that countries choose to share with the WHO under the terms of the PIP Framework's SMTAs. The confusion will remain even if the PIP Framework is formally recognised as a specialized international ABS instrument.

This article has not touched on the potential process for recognition of a specialized instrument, but rather focused on the form that a specialized instrument would need to take in order to qualify for that recognition. But the mechanics of recognition are important. The Meeting of the Parties to the Nagoya Protocol is likely the only body that could possibly recognise a specialized instrument because the specialized instrument provision is only found in the Nagoya Protocol. There is no equivalent provision in the CBD, so states parties to just the CBD are not bound to recognise the existence of any specialized instrument. It is not clear whether recognition would mean that the 123 contracting parties to the Nagoya Protocol would have to treat the PIP Framework as a specialized instrument under their domestic ABS legislation while the remaining 73 states parties to the CBD alone (as well as the United States and the Holy See which are party to neither agreement) would not have to accept the PIP Framework's new found status as a specialized instrument at all. Thus, recognition of the PIP Framework as a specialized ABS instrument would not necessarily change anything for more than a third of WHO member states.

All of this indicates that recognition as a specialized instrument would be a purely symbolic (perhaps political) gesture, not able to alter the legal status of the PIP Framework. That is not to say that symbolic gestures are unimportant. We have made this point before, and we want to reiterate it here: access to viruses and other pathogen samples need not be connected to the sharing of vital medicines and vaccines. These issues are both public health issues, but they do not need to be linked through the ABS transaction. The PIP Framework crystallised these separate issues as a single ABS issue, and ABS has its home in the UN system with the CBD and Nagoya Protocol. This is potentially why recognition as a specialized instrument is so appealing for the PIP Secretariat and the WHO more broadly. It seems like an easy fix. If the PIP Framework is considered a specialized ABS instrument under the

181 See eg WHO (n 173 above) 9.

182 CBD (n 4 above) 2.

Nagoya Protocol, then the WHO remains relevant in the discussions about pathogen sample sharing and the Nagoya Protocol ceases to present a conceptual challenge to the PIP Framework, one where the ultimate goals of both instruments are potentially at odds (conservation of genetic resources versus eradication of disease). It also means the PIP Framework would have the international ABS stamp of approval and an endorsement of the suitability of the transactional mechanism for the sharing of pathogens *and* the sharing of pharmaceuticals, and the WHO would no longer have to grapple with the unpalatable reality that it is encouraging countries to use their pathogen samples as currency to purchase the life-saving vaccines and medicines to which they should already have access.